AUG 15 1996

K951033

CANDELA DYNAMIC COOLING DEVICE
510(k) SUMMARY

GENERAL INFORMATION

Classification: Laser Surgical Instrument Accessory for use in General and Plastic Surgery and in Dermatology

Common Name: Skin refrigerant

Predicate Device: Cool Laser Optics Device and numerous Cold Packs

DESCRIPTION

Candela's Dynamic Cooling Device consists of 1) a source of skin refrigerant fluid (CFC R-12), 2) an electronically controlled solenoid delivery valve, and 3) electronic timing circuitry. The Dynamic Cooling Device is connected in line with an SPTL laser's triggerswitch system so that activation of the triggerswitch controls the delivery of a pulsed spray of CFC R-12 just prior to the delivery of a laser pulse. The pulsed spray of skin refrigerant cools the skin as it evaporates. Thermal injury to non-vascular structures is minimized and pain associated with the laser treatment is reduced.

INTENDED USE STATEMENT

The intended use of the Candela Dynamic Cooling Device is to minimize thermal injury to non-vascular skin structures during laser therapy of benign cutaneous vascular lesions, and to reduce pain associated with laser treatment.

TESTING

Candela's Dynamic Cooling Device has undergone and passed testing during its development designed to assess the performance of components and finished devices, including dimensional testing, functional properties, function according to its intended use, ease of use and durability.

PRODUCT DEVELOPMENT REVIEW

Design reviews conducted during development of this device verify the appropriateness of materials and design selection.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Candela's Dynamic Cooling Device is substantially equivalent to the Cool Laser Optics device and to numerous legally marketed Cold Packs on the basis of similarities in operating principles, intended use and functional performance.